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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,338	10/07/2003	Samuel Achilefu	MRD-59CP (1520.1 US)	5451

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EXAMINER

JONES, DAMERON LEVEST

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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01/11/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/680,338	Applicant(s) ACHILEFU ET AL.	
	Examiner D. L. Jones	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6-8,11-14,16,17 and 19-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4, 6-8, 11-14, 16, 17, and 19-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) ☒ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) ☐ Notice of Informal Patent Application |
| 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) ☐ Other: _____ |

WITHDRAWAL OF FINALITY

1. The finality of the office action mailed 8/6/07 is WITHDRAWN in view of the new grounds of rejections below.

ACKNOWLEDGMENTS

2. The Examiner acknowledges receipt of the amendment filed 12/11/07 wherein claims 1, 7, 8, 14, 16, 17, 19, 20, and 22-25 were amended and claims 2, 5, 9, 10, 15, and 18 were canceled.

Note: Claims 1, 3, 4, 6-8, 11-14, 16, 17, and 19-29 are pending.

RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS

3. The Applicant's arguments and amendment filed 12/11/07 to the rejection of claims 1, 6, 7, and 27-29 have been fully considered and deemed persuasive.

Therefore, all outstanding rejections are hereby withdrawn.

NEW GROUNDS OF REJECTIONS

Double Patenting Rejection

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1, 3, 4, 6-8, 11-14, 16, 17, and 19-29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 11/779,088. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to compositions and uses thereof wherein the composition comprises a compound of formula I as set forth in the instant invention (Note: W6 and x6 are both sulfur atoms). The claims differ in that 11/779,088 is not limited to compounds wherein W6 and X6 are sulfur. Thus, it would be obvious to one of ordinary

skill in the art at the time the invention was made that the instant invention is encompassed by the claims of 11/779,088.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

112 Second Paragraph Rejections

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 20-22 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 20-22: The claims as written are ambiguous because they depend on canceled claim 18.

Claim 22: The claim as written is ambiguous because it should depend from claim 8 which is directed to an optical imaging method. Thus, it is unclear whether or not the additional method step should be 'selected from...optical method' or if 'optical method' should not have been included in the Markush grouping.

Claim 24: The claim as written is ambiguous because of the awkward claim language. In particular, it is unclear whether or not Applicant actually intended to insert the term 'further' before the term 'comprising' in line 3.

102 Rejections

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 3, 6, and 27-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al (WO 96/00902).

Lee et al disclose cyanine dyes for use as fluorescence labels. The cyanine dyes have a fluorescence absorbance of between about 500 and 900 nanometers (see entire document, especially, abstract; page 5, lines 5-10). In particular, Lee et al disclose a dye that fulfills the requirements of Applicant's invention. Specifically, on page 13, the first dye on the page, fulfills Applicant's requirement when W6 and X6 = sulfur; V6 = single bond; R58 = halogen; a6 = 1; b6 = 1; R46 – R57 = hydrogen; A6, B6, and E6 = CRc wherein Rc = hydrogen; and Z6 and Y6 = (CH₂)_dCO₂T wherein d = 5 and T = independently a hydrogen or a negative charge. The absorbance and fluorescence emission wavelength of the cyanine dye Hence, both Lee et al and Applicant disclose overlapping subject matter.

10. Claims 1 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Tolmachev et al (Khimiya Geterotsiklicheskikh Soedinenii, 1976, Vol. 2, pages 175-178).

Tolmachev et al disclose tricarboyanines in chromophores (see entire document, especially, abstract). In particular, Tolmachev et al disclose two dyes compounds/compositions (Compounds XIX and X) which fulfill the requirement of Applicant's invention. Compound X (page 154) fulfill the requirements of the instant

invention when W6 and X6 = sulfur; Z6 = alkyl; a6 = 1; b6 = 1; V6 = single bond; R46 - R58 = hydrogen; E6 = CRc wherein Rc = hydrogen; A6 = CRc wherein Rc = hydrogen; D6 = single bond; B6 = CRc wherein Rc = hydrogen. Compound XIX (page 154) fulfill the requirements of the instant invention when W6 and X6 = sulfur; Z6 = alkyl; a6 = 1; b6 = 1; V6 = single bond; R46 - R58 = hydrogen; E6 = CRc wherein Rc = hydrogen; A6 = CRc wherein Rc = hydrogen; D6 = single bond; B6 = oxygen. Hence, both Applicant and Tolmachev et al disclose overlapping subject matter.

11. Claims 1 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Slominskii et al (Ukrainskii Khimicheskii Zhurnal, Russian Edition, 1980, Vol. 46, No. 1, pages 61-63).

Slominskii et al disclose nonamethinecyanines with cyclic groups in the polymethine chain (see entire document, especially, abstract). In particular, Slominskii et al disclose two dye compounds/compositions that fulfill the requirements of the instant invention. Compound XII (page 62) fulfills the requirements of the instant invention when W6 and S6 = sulfur; b6 = 1; a6 = 2; Z6 = alkyl; V6 = single bond; R46-R58 = hydrogen; A6, B6, and E6 = CRc wherein Rc = hydrogen; and D6 = single bond. In addition, Slominskii et al disclose Compound XV (page 62) fulfills the requirements of the instant invention when W6 and S6 = sulfur; b6 = 1; a6 = 2; Z6 = alkyl; V6 = single bond; R46-R58 = hydrogen; A6 and E6 = CRc wherein Rc = hydrogen; B6 = oxygen; and D6 = single bond. Hence, both Applicant and Slominskii et al disclose overlapping subject matter.

12. Claims 1, 3, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Narayanan et al (Journal of Organic Chemistry, 1995, Vol. 60, No. 8, pages 2391-2395).

Narayanan et al disclose a method for synthesizing heptamethine cyanine dyes which are used as near infrared fluorescent labels (see entire document, especially, abstract). In particular, Narayanan et al disclose Compound 5h (page 2392) that fulfills the requirements of Applicant's invention wherein W6 and X6 = sulfur; R46 - R57 = hydrogen; a6 = 1; b6 = 1; V6 = single bond; R58 = halogen; Y6 = alkyl; and Z6 = alkyl. Hence, both Applicant and Narayanan et al disclose overlapping subject matter.

13. Claims 1 and 27-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Shiratsuchi et al (EP 924,724).

Shiratsuchi et al disclose dye compounds (see entire document, especially, abstract). In particular, Shiratsuchi et al disclose Compound (34), page 13, that fulfills the requirements of Applicant's invention when W6 and X6 = sulfur; Z6 and Y6 = (CH₂)_dCO₂T wherein d = 1 and T = hydrogen; V6 = single bond; R46 - R58 = hydrogen; A6 and E6 = CR_c wherein R_c = hydrogen; and B6 = CR_cR_d wherein R_c and R_d = alkyl. Hence, both Applicant and Shiratsuchi et al disclose overlapping subject matter.

14. Claims 1 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Slominskii et al (Ukrainskii Khimicheskii Zhurnal, Russian Edition, 1974; Vol. 40, No. 6, pages 625-629).

Slominskii et al disclose tricarboyanines with hydrocarbon rings (see entire document, especially, abstract). In particular, Slominskii et al disclose Compounds X and XI (page 627) which meet the requirements of the instant invention. Compound X fulfills the requirements of the instant invention when W6 and X6 = sulfur; Z6 = alkyl; a6 = 1; b6 = 1; V6 = single bond; R46 - R58 = hydrogen; E6 = CRc wherein Rc = hydrogen; A6 = CRc wherein Rc = hydrogen; D6 = single bond; B6 = CRc wherein Rc = hydrogen. In addition, Slominskii et al disclose Compound XI that fulfill the requirements of the instant invention when W6 and X6 = sulfur; B6 = alkyl; R46 - R58 = hydrogen; V6 = single bond; and wherein one of B6, A6, or E6 = alkyl and the other two variables are CRc wherein Rc = hydrogen. Hence, both Applicant and Slominskii et al disclose overlapping subject matter.

COMMENTS/NOTES

15. The restriction between the product claims (Applicant's elected Group XII wherein both W6 and X6 are sulfur atoms) and the methods of use thereof have been WITHDRAWN. Thus, Applicant's elected product claims have been rejoined with the method claims.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


D. L. Jones
Primary Examiner
Art Unit 1618

December 31, 2007